

SPL Process ER/DL Meeting Meeting Minutes May 17, 2017

Chair of today's meeting: Pat Cowall-Hanover

Teleconference information (Herb O'Brien):

USA : 412-777-7525

Conference ID: 502 567 562

Meeting schedule: Every other Wednesday, 1 pm ET

Link to the SPL wiki:

<http://spl-work-group.wikispaces.com/share/view/51351516>

Agenda:

1. Announcement: Pat Cowall is taking a voluntary package from Lilly and will be retiring on May 31, 2017. Herb O'Brien and Ben Harpster are ready, willing, and very able to carry us on into the future!
2. Monica Arcos (Baxter): We have a situation where we manufacture a drug product at one of our facilities for another company. We understand that given the new final rule, we are required to drug list; however, we would like to gain clarification on who is required to assign the NDC and whose labeler code must be used when we, the manufacturer, drug lists.

Meeting discussion:

- There are 2 drug listings required by the manufacturer:
 - Manufacturing drug listing: as the manufacturer, using the manufacturer's labeler code
 - Old category name: Approved Drug Product Manufactured Exclusively for Private Label Distributor
 - New category name: Approved Drug Product Manufactured Under Contract
 - If the manufacturer makes the same product for multiple PLDs: they can include all PLD labels in the one drug listing.
 - If the manufacturer markets the same product and drug lists final product for themselves: FDA recommends that manufacturers do this drug listing, but it is not required.
 - Final product for the private label distributor: on behalf of the PLD, using the PLD's labeler code.
 - Manufacturers are responsible for this, per regs, but the PLDs frequently do this for themselves. Mfg's should work with the PLDs to determine who will do this and what NDC should be used.

3. Howard Shatz: Export only question - For an export only listing, if the listing is for a single product (e.g. Very Good Toothcleaner) in one package (e.g. 90 ml) but with 4 different labels for different language translations, can the SPL submission have just the one NDC code for the product with only one label image in the drug listing?

Meeting discussion:

- If it is being exported, you are listing as a manufacturer
- Regs say “representative set of labels”
- Use only 1 NDC number
- Most companies include only the English version. They add a comment saying that this is being manufactured/shipped using labels in multiple languages, and only a representative label in English is provided.

4. Mary Beth Kline: Can we discuss the difference between the 2 business operations – ‘Manufacture’ and ‘FDF Manufacture’. Our labeling group has brought it to my attention as to whether we should be using FDF Manufacture instead of Manufacture. What is everyone else using?

Meeting discussion:

- The business operations qualifiers includes all values for drug listing, GDUFA self identification, and labeler codes.
- Manufacture: is used in Rx drug listing.
- FDF Manufacture: This is used only for the purpose of GDUFA self identification.

Nathalie Draus sent the following information: The “FDF Manufacture” business operation is only for GDUFA Self-Identification SPLs, and would not apply to regular Establishment Registrations. For the purposes of GDUFA Self-Identification, the MANUFACTURE business operation would pertain to “The act of making something (a product) from raw materials.” The FDF (Finished Dosage Form) MANUFACTURE business operation would pertain to “The act of making a product as ready to be utilized or consumed by the end user.”

5. Jean Lensing: We would like to discuss/clarify how firms are managing the timing of de-listing products and how firms are managing images in the PDP for de-listed products. At what point in time are firms entering the marketing status of “completed” and applying a future marketing end date?
- When the information about the last expiration date becomes internally available (i.e. possibly several months in advance of the expiration of last lot)
 - At the point of expiration of the last lot (more real time)
 - After the expiration of the last lot (we are required to “delist” before the last lot expiration but do we have 30 days to do this if it hasn’t already been done?)
 - Are any firms using anything other than last expiration date for the marketing end date?

Meeting discussion:

- The market end date should be the expiration of the last lot.
- People can enter this date at many times: many companies enter the date in the SPL whenever they learn about it, and they leave the data and PDP image in the drug listing until after the expiration date.
- You need to put the expiration on both the package level and on the product level when the last lot expires.
- The NDC will automatically be archived / removed from the NDC directory when the end date is reached.
- There was discussion about whether you need to postdate the market end date – in order to allow for reimbursements.
 - The govt price reporting group with pharma companies also provide these dates to govt agencies and they have a field for 1 year after market end date.
 - Several years ago we had a discussion with CMS and they allow extra time for processing reimbursement claims.

For the required image in the PDP of a product that has an end marketing date,

- Are firms leaving the existing product image in the PDP
- Are firms updating the SPL to remove the image and inserting a placeholder “no image available” image?
- If firms are updating the image (removing image and adding “no image available” image, at what timeframe are they doing so?

Meeting discussion:

- The PDP and data have to remain in the drug listing until the expiration of the last lot.

6. Jean Lensing: Is there any additional understanding/information on the Annual Certification of Drug Listings as required by Final Rule.

- Is the submission of the Labeler Code file all that is needed to certify listings are current?
- What are the mechanics of a “no change” listing? Is it as easy as updating the Effective Date for the SPL and regenerating a new document id and SPL version?

Meeting discussion:

- No news yet. The eDRLS group will provide instructions once their process is final.
- OLD NDC numbers: Post meeting note from Kate Detweiler:
 - The final rule says that all NDCs must be unique. You can request a listing of NDC numbers from the FDA – in particular from the old system.
 - In the past, our NDCs have been considered “valid” if we had drug listed them in the old system. NDC have never before “expired.” This will not be true in the future with the new rule. The new rule now says that NDCs must now be certified annually. This means that any NDCs registered only in paper will be automatically delisted.
 - KEY point: be sure that all of your “paper listed” NDCs are drug listed electronically.

7. Jean Lensing: What about no change listing?

Meeting discussion:

- Can submit old file – and just put a new date on the listing and a new doc ID.

8. What happens if you find 2 products with the same NDC in the marketplace. Do you have to pull the product off the market if you find duplicate NDCs?

Meeting discussion:

- Check the NDC directory to see which product is drug listing. The product that isn't drug listed is misbranded – subject to all the consequences outlined in the regulations associated with misbranded product.
- Note: The manufacturer is responsible for drug listing and for the misbranded product.

Announcements:

1. The 2017 DailyMed Jamboree will be on Tuesday, September 19th, in Bethesda.
2. FDA announced the inclusion of sample designation in our drug listings. Per Charisse, this is available for both Human drug products and Veterinary product. This information was included in a separate correspondence several weeks ago. The coding is straight forward – ie using a new data value for the marketing category:

Per Lonnie, the elements are the same as the one for the marketing,

- the term “marketing” is replaced by the term and code for drug sample.
- Packages that are samples are marked with a marketingAct with the code C96974 instead of the default marketing act code C53292.

Per Leyla: Packages may now be marked as being a drug sample rather than regularly marketed for sale. Packages that are samples are marked with a marketingAct code C96974 instead of the default marketingAct code C53292:

```
<asContent>
  <containerPackagedProduct>...</containerPackagedProduct>
  <subjectOf>
    <marketingAct>
      <code code="C96974" codeSystem="2.16.840.1.113883.3.26.1.1"/>
      <statusCode code="active"/>
    </marketingAct>
  </subjectOf>
</asContent>
```

```
<effectiveTime>  
  <low value="20040120"/>  
</marketingAct>  
</subjectOf>
```

Except for the code (in Red) the other data elements could be entered under the same rules for a regular marketed package size.

Coding for veterinary products is comparable.

Per Lonnie, the drug sample package code may be utilized for animal drug product SPL files.

One would just use the NCI concept code "C96974" instead of "C53292"

```
</containerPackagedProduct>  
<subjectOf>  
  <marketingAct>  
    <code code="C96974" codeSystem="2.16.840.1.113883.3.26.1.1"/>  
  </marketingAct>  
</subjectOf>
```

Note: The new code is not yet on the SPL Resources website. Per Leyla: The new Drug Sample code C96974 should pass the validation rules without a manual override. Also, this option is available for Human Prescription Drug Label, Human OTC Drug, and Veterinary Label document types.